IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Whitbourne *et al.*

Art Unit: 1618

Application No: 09/834,307

Examiner: Micah Paul YOUNG

Confirmation No: 3036

Filed: April 12, 2001

Atty. Docket No: 32286-192724

Customer No:
26694
PATENT TRADEMARK OFFICE

For: TARGETED THERAPEUTIC AGENT RELEASE DEVICES AND METHODS OF MAKING AND USING THE SAME

DECLARATION UNDER 37 C.F.R. § 1.132

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Alexandra M. Chamberlain, declare as follows:

1. I have over 10 years of experience in the field of medicated coatings and medical devices having such coatings.

2. My credentials are set forth in my CV, a copy of which is attached hereto as Appendix A. I am currently employed as a Research Associate by Angiotech Pharmaceuticals, Inc., which I understand to be the owner of U.S. patent application no. 09/834,307 ("the '307 application").

3. I am familiar with the '307 application and I understand the subject matter disclosed and claimed therein.

4. I have also reviewed the non-final Office Action dated August 23, 2007, and I understand that the Office Action has applied U.S. Patent No. 5,980,550 to Eder *et al.* (hereinafter "Eder") as the primary reference in rejecting all of the pending claims 23-67 and 69-83 in the '307 application.

5. It is my understanding that, in rejecting the claims, the Office Action cites FIG. 2 of Eder as showing a coating "bridging" from one edge or surface to another across an opening as recited in at least independent claims 23, 43, 45, 50, 61, and 77.

6. It is my belief, however, that, Eder cannot be fairly and reasonably read to teach or suggest any such "bridging." That is, notwithstanding that which the Office Action purports to be shown in FIG. 2 of Eder, I do not believe that one having ordinary skill in the art of coatings and/or coated devices would understand Eder to teach or suggest a coating that bridges from one edge or surface to another across an opening. Instead, it is my belief that FIG. 2 is merely a poorly crafted schematic illustration or cartoon intended only to show a two-layer coating on a coil and which appears to improperly depict a side view of the coil with a cross-section of the coating. In my view, FIG. 2 fails to take into account the three-dimensional nature of the coil. Accordingly, in my opinion, FIG. 2 of Eder is not representative of any "bridging" of the coating in the open areas between adjacent turns of the coil and any interpretation of FIG. 2 as teaching as much is misdirected.

7. It is also my belief that other experts and persons experienced in the field of medicated coatings and medical devices having such coatings would not understand Eder, and in particular FIG. 2 of Eder, as teaching or suggesting any coating "bridging from one edge or surface of the substrate to another across an opening."

8. Moreover, based on a fair and reasonable reading of the written disclosure of Eder, it is my opinion that a proper side view of the coil showing the two-layer coating in cross-section would look more like that shown in the drawing attached hereto as **Appendix B**.

9. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

Date: January 31, 2008

Alexandra M. Chamberlain

Alexandra M. Chamberlain

DC2-925490v2

APPENDIX A

Curriculum Vitae
Alexandra M. Chamberlain
Research Associate

Education:

B.S. Chemistry and Biology	State University of New York College at Brockport, May 1991.

Summary of Professional Experience:

Dates	Title/Company
1/05 – Present	Research Associate Angiotech-Rochester R&D
7/03 – 12/31/04	Senior Scientist STS Biopolymers, Inc., R&D
11/02 – 7/03	Scientist II STS Biopolymers, Inc., R&D
7/01 – 11/02	Research Scientist STS Biopolymers, Inc., R&D
11/98 - 7/01	Formulation Scientist STS Biopolymers, Inc., R&D
5/98 - 11/98	Laboratory Technician, University of Rochester Medical Center, Center for Oral Biology
3/93 - 1/98	Research Scientist, Eastman Kodak Company, Imaging Research and Advanced Development, Photo Science Research
7/91 – 3/93	Research Scientist, Eastman Kodak Company, Corporate Research Laboratories
6/90 – 5/91	Undergraduate Researcher, SUNY Brockport, Chemistry Department

At Angiotech, Ms. Chamberlain has contributed to formulation activities for anti-thrombogenic, anti-restenotic and anti-infective coating research. Other duties and responsibilities include:

- Developing and conducting new or improved coating formulations or chemistries for medical devices, including MEDI-COAT® formulations to inhibit thrombosis and restenosis.
- Developing or improving devices or methods
- Serving on cross-departmental teams to solve manufacturing/operations related problems

- Assisting in the transfer of coating processes from R&D to manufacturing
- Assisting with regulatory submissions such as RFD, IDE, 510(k), CE Mark
- Conducting and monitoring *in vivo* and *in vitro* evaluation experiments including testing, formulation, and screening of coatings and coated products.
- Conducting patent or literature searches
- Assisting in filing for patents
- Supervising and mentoring Research Associates

Publications, Presentations, and IP:

Publications

- B.K. Coltrain, C.J.T. Landry, J. M. O'Reilly, **A.M. Chamberlain** *et al:* "The Role of Trialkoxysilane Functionalization in the Preparation of Organic-Inorganic Composites", *Chemistry of Materials*, **1993**, Volume 5, Number 10, 1445-55.
- Eastman Kodak Internal Documents:
  - Four (4) Technical Reports on composites, blends.
  - Nineteen (19) Polymer Commentary Articles on polymeric supports, lubricants.

Podium Presentations

- A.M. Chamberlain, J. Dowd, D. Stella, and D. Wadsworth: Preparation and Reactions of Aminocyclopropenones. 36th Annual Undergraduate Research Symposium, Rochester, New York, April 1991.
- S. F. Rosebrough, S. Berg, **A. M. Chamberlain**, D. Hullihen, R. Mysliwiec, R. Whitbourne: Elution Rate of Paclitaxel from Polymer Coatings, Society for Biomaterials, Saint Paul, Minnesota, April 2001.
- S. F. Rosebrough, A. M. Chamberlain, M. Violante, R. Whitbourne, Extraction Rate of Heparin Benzalkonium (HBAK) from MEDI-COAT™ Polymers, Society for Biomaterials, Saint Paul, Minnesota, April 2001.
- A.M. Chamberlain, S. F. Rosebrough, R. J. Whitbourne, M. R. Violante, Heparin and Paclitaxel Release from MEDI-COAT™ Polymer Coatings, Surfaces in Biomaterials, Scottsdale, Arizona, August 2001.
- M. Calistri-Yeh, S. F. Rosebrough, **A. M. Chamberlain**, W. Donish and R. Whitbourne, Drug-Eluting Polymer Coatings for Cardiac Stents, American Chemical Society National Meeting, Boston, MA, August 2002.
- S. F. Rosebrough, **A. M. Chamberlain**, R. Whitbourne, *In Vitro* and *In Vivo* Evaluation of an Anti-Thrombogenic Polymer Coating, BioInterface, Scottsdale, Arizona, September 2002.
- Millie Calistri-Yeh, Robert Baier, **Alexandra Chamberlain**, *et al* Surface Analysis of Lubricious Coatings for Medical Devices, American Chemical Society National Meeting, Polymer Materials Science and Engineering, New Orleans, Louisiana, March 2003.
- A.M. Chamberlain, S. F. Rosebrough, M. Calistri-Yeh, R. J. Whitbourne, Anti-Thrombogenic Drug Delivery Coatings for Indwelling Catheters, Society for Biomaterials, Reno, NV, May 2003.

Posters

- S. F. Rosebrough, X. Zhang, **A. M. Chamberlain**, M. Violante, R. Whitbourne: Sustained Anticoagulation with Catheters Coated with Heparin MEDI-COAT™ Polymer, Biomaterials Sixth World Congress, Hawaii, May 2000.
- S. F. Rosebrough, G. L. Oltean, J. C. Swartz, **A. M. Chamberlain**, D. R. Jones. A Three-Dimensional Polymeric Surface for Genomic and Proteomic Microarrays, Society for Biomaterials, Tampa, Florida, April 2002.
- J. E. Perry, S. F. Rosebrough, **A. M. Chamberlain**, R. J. Whitbourne, *In Vitro* Evaluation of an Anti-Infective Polymer Coating, Society for Biomaterials, Reno, NV, May 2003.

IP

- U.S. Patent Application No. 10/662,877, filed Sept. 16, 2003, Medicated Stent Having Multi-layer Polymer Coating, R. J. Whitbourne, D. G. Hullihen, **A. M. Chamberlain**, S. F. Rosebrough, M. Calistri-Yeh.

APPENDIX B